

Communicable Disease Unit
Prevention Program
340B Drug Pricing Program
External Guidance

Additional information and copies may be obtained from:

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Introduction

The Wyoming Department of Health (WDH) Communicable Disease Unit (CDU) participates in the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program. The 340B Drug Pricing Program enables covered entities to purchase medications and testing supplies at a reduced rate stretching scarce Federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services. Eligible health care organizations/covered entities are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance Programs (ADAP).

Enrollment and Recertification

All eligible organizations/covered entities must register and be enrolled with the 340B Program and comply with all 340B Program requirements to receive medications and testing supplies from the CDU. The CDU's authorizing official completes the online registration process. New registrations are accepted October 1-15 for an effective start date of January 1; January 1-15 for an effective start date of April 1; April 1-15 for an effective start date of July 1; and July 1-15 of each year for an effective start date of October 1.

HRSA requires entities to recertify their information as listed in the HRSA 340B Database annually. The CDU's authorizing official completes the recertification annually by following the directions in the recertification e-mail sent from HRSA to the authorizing official by the requested deadline.

Definitions

To be eligible to receive 340B-purchased drugs, patients must receive health care services other than drugs from the 340B covered entity.

An individual is a patient of a 340B covered entity only if:

- the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; *and*
- the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; *and*

- the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

Individuals with Medicaid may not receive any medications purchased through 340B. Individuals with private insurance may receive medications purchased through 340B, however, priority should be given to individuals without insurance.

- For a list of complete definitions reference,
<https://docs.340bpvp.com/documents/public/resourcecenter/glossary.pdf>
- For a full list of eligible organizations/covered entities reference,
<https://opanel.hrsa.gov/opa/CESearch.aspx>
- To contact the 340B Prime Vendor Program for help reference,
apexusanswers@340bpvp.com
- To reference a guide to Recertification,
https://opanel.hrsa.gov/OPA_MOD/MANUALS/PUBLIC/CERecertify.pdf

Medication Information

The CDU orders medications from an approved vendor for treatment of sexually transmitted diseases (STDs) and testing supplies for Tuberculosis (TB). Supplies are ordered on an as needed basis from the vendor and monitored by the Communicable/Prevention and Health Promotion (PHP) Unit Support personnel. The medications that are available include, but are not limited to:

- Azithromycin
- Bicillin
- Ceftriaxone
- Doxycycline
- Suprax
- Xylocaine
- Aplisol
- Syringes

Facility Eligibility

Each facility that receives treatment medications and TB testing supplies from the CDU must be registered with the 340B Drug Pricing Program. This registration is completed annually during the first fifteen (15) days of each quarter, with an effective start date of the first day of the next quarter. For example, if a facility registered with the 340B Drug Pricing Program on October 1 they will be able to receive medications at the 340B Pricing from their vendor on January 1. The CDU will register all Public Health Nursing (PHN) offices under the Unit's umbrella as the authorizing official. All other facilities must register online through HRSA 340B Drug Pricing Program. This registration must include the facility primary contact and authorizing official information.

All facility staff involved in the administration, ordering, or dispensing of 340B medications must complete the following online trainings:

- 1) <https://www.brainshark.com/apexus/TopFive340BBasics>
- 2) <https://www.apexus.com/solutions/education/pvp-education/340b-u-ondemand>

Facility Medication Ordering Procedure

The facility will complete a medication order form to request STD medications and TB testing supplies. The facility can obtain a medication order form here:

TB testing supplies: https://health.wyo.gov/wp-content/uploads/2016/04/Supplyorderform_021016.pdf

STD medications: https://health.wyo.gov/wp-content/uploads/2016/02/61-18308_AntibioticOrderForm2016DT.pdf

When a clinic/facility has completed the order form, it is then emailed to cdusupplies@wyo.gov. This email is monitored by the CDU/PHP Unit Support personnel and all orders are filled by a pharmacist. Once the order form is received the Unit Support personnel acknowledges the order, prints mailing labels and the pharmacist fills each order for the specific facility. Orders are mailed on Monday, Tuesday, and Wednesday to ensure timely delivery.

Each facility ordering medications will be monitored by CDU personnel.

Medication Reporting Procedure

The CDU requires that all 340B medications either purchased from an approved vendor or received from the CDU are reported to the CDU, as all medications must be accounted for. The CDU requires that a facility complete the “Medication Log Form,” which is available on the CDU website. Form is available [here](#). All STD treatment medications must be reported to the CDU by the seventh (7th) day of every month for the previous month’s medication usage. The Medication Log Form may be submitted to cdusupplies@wyo.gov or 307-777-5279 (fax). Non-compliance with reporting requirements may result in delays of medication orders.

The TB testing supplies must be reported into the WyIR reporting system by the seventh (7th) day of every month. The WyIR reporting guidance and WyIR data entry training is available through the CDU and must be completed before any facility personnel can enter information into the WyIR.

Returned Medication Procedure

In the event that a clinic/facility has medications that they have not used by the expiration date the facility must return the medication back to the CDU. The returned medication must be submitted with the “Returned Medication Log” and shipped directly to the Communicable Disease Unit for disposal. The “Returned Medication Log” is available on the CDU website. Form is available [here](#). All medications returned to the CDU will be tracked by CDU/PHP Unit Support personnel.

Corrective Action Plan

The CDU requires that all rules and regulations set by HRSA and the CDU are followed. Facilities that do not follow all rules and regulations set by HRSA and the CDU will be placed on a corrective action plan. The corrective action plan is a tool used by the CDU and facilities to determine a set of guidelines and procedure so that the error does not happen again. Both the CDU and the facility will work together to develop the tools for the corrective action plan. It is important to note that if the facility does not follow the corrective action plan the facility may be responsible for payment of the difference in cost of medications from 340B prices to retail prices from the medication vendor. Steps of the corrective action plan will be the following:

1. CDU and facility will discuss error(s) responsible for corrective action plan and work together to develop a plan to correct errors and prevent errors from happening in the future.
2. Implementation of corrective action plan with facility and CDU.
3. The facility will have thirty (30) days to implement the corrective action plan and correct all identified errors.

4. The facility will report to the CDU of progress of action plan at the end of the thirty (30) day period.

5. CDU will review the progress report to determine if the identified errors have been corrected. If the errors have been corrected, the facility may exit the corrective action plan.

If the identified errors have not been sufficiently addressed, the facility and CDU will complete a revised corrective action plan and start the process over.

Facility Audit Procedures

External Audits – facilities will be subject to external audits from HRSA. The CDU will receive notice from HRSA regarding audit sites and will notify facilities immediately.

Internal Audits – The CDU will audit facilities receiving 340B medications for all medications purchased through 340B. Audits may be conducted in-person or virtually by CDU staff. Facilities will receive notification of upcoming audit at least sixty (60) days prior to the date of the audit. Facilities will be required to provide information pertaining to the administration of 340B for the audit at least thirty (30) days prior to the date of the audit. Facilities will receive an audit report from CDU no more than sixty (60) days after the completion of the audit.

Expedited Partner Therapy Procedure

The CDU will provide medications for Expedited Partner Therapy (EPT). Facilities that order and provide EPT will keep all EPT medications separate from 340B. 340B medications may not be used for EPT. Medications supplied from the CDU for EPT will be placed on a medication order form specific for EPT. Facilities must track EPT medications on the “EPT Reporting Log” which is available on the CDU website. The EPT reporting log is available [here](#).

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